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| 10/599,479 | 12/19/2006 | Masayoshi Shichiri | 4439-4047 | 9587 |

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| EXAMINER | |
|---|---|
| KAM, CHIH MIN | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1656 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ptopatentcommunication@lockelord.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/599,479 | SHICHIRI, MASAYOSHI | |
| | Examiner | Art Unit | |
| | CHIH-MIN KAM | 1656 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *08 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *10,11 and 15* is/are withdrawn from consideration.

5)☒ Claim(s) *1* is/are allowed.

6)☒ Claim(s) *2-5,7,9 and 12-14* is/are rejected.

7)☒ Claim(s) *6 and 8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 September 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *sequence match*.

## DETAILED ACTION

### *Status of the Claims*

1. Claims 1-15 are pending.

Applicants' amendment filed September 8, 2009 is acknowledged. Applicants' response has been fully considered. Claims 1-4, 6-9 and 12-13 have been amended. Claims 10-11 and 15 are non-elected inventions and are withdrawn from consideration. Therefore, claims 1-9 and 12-14 are examined.

### ***Withdrawn Informalities***

2. The previous objection to the specification is withdrawn in view of applicants' amendment to the specification, and applicants' response at page 9 in the amendment filed September 8, 2009.

### ***Withdrawn Claim Objections***

3. The previous objection to claims 6-9 is withdrawn in view of applicants' amendment to the claims, and applicants' response at page 9 in the amendment filed September 8, 2009.

### ***Withdrawn Claim Rejections - 35 USC § 101***

4. The previous rejection of claims 1-4 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, is withdrawn in view of applicants' amendment to the claims, and applicants' response at page 10 in the amendment filed September 8, 2009.

### ***Withdrawn Claim Rejections - 35 USC § 112***

5. The previous rejection of claims 1 and 3 under 35 U.S.C. 112, first paragraph, written description, is withdrawn in view of applicants' amendment to the claims, and applicants' response at pages 10-13 in the amendment filed September 8, 2009.

6. The previous rejection of claims 1-5 and 12-14 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' amendment to the claims, and applicants' response at pages 14-15 in the amendment filed September 8, 2009.

***Abstract***

7. The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 2, 4, 5, 7, 9 and 12-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 2, 4, 5, 7, 9 and 12-14 are drawn to an isolated peptide generated from the following amino acid sequence (A) or (B) as a result of further cleavage or modification by a processing enzyme and has a cardioinhibitory activity or hypotensive activity: (A) the amino acid sequence of SEQ ID NO:2; (B) an amino acid sequence wherein one to five amino acids are deleted, substituted or added in the sequence shown by SEQ ID NO: 2, wherein a peptide consisting of the amino acid sequence has a cardioinhibitory activity or hypotensive activity; an

isolated DNA encoding a peptide generated from the following amino acid sequence (A) or (B) as a result of further cleavage or modification by a processing enzyme and has a cardioinhibitory activity or hypotensive activity; a method of screening a cardioinhibitory factor or hypotensive factor using the peptide; a method of screening an inhibitor of a cardioinhibitory activity or an inhibitor of hypotensive factor using the peptide; and a cardioinhibitory /hypotensive agent comprising the peptide.

In *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1938, the Court of Appeals for the Federal Circuit has held that "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials". As indicated in MPEP § 2163, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus. In addition, MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

While the specification indicates that the present invention relates to a peptide consisting of the amino acid sequence of SEQ ID NO:2 and an amino acid sequence related to SEQ ID

NO:2; a DNA encoding a peptide of SEQ ID NO:2 and an amino acid sequence related to SEQ ID NO:2; a DNA consisting of the nucleotide sequence of SEQ ID NO:1 and a nucleotide sequence related to SEQ ID NO:1 (paragraphs [0009], [0010]), the specification does not sufficiently describe a genus of variants for peptides generated from the following amino acid sequence (A) or (B) as a result of further cleavage or modification by a processing enzyme and has a cardioinhibitory activity or hypotensive activity, or for nucleotides encoding the peptides: (A) the amino acid sequence of SEQ ID NO:2; (B) an amino acid sequence wherein one to five amino acids are deleted, substituted or added in the sequence shown by SEQ ID NO: 2, when there is substantial variation within the whole genus of peptides obtained by the further cleavage or modification of (A) or (B) by process enzymes. Although the specification discloses specific peptide fragments of SEQ ID NO:2 such as residues 1-20, 5-24 and 2-13 of SEQ ID NO:2 that are functional (paragraph [0014]), there is no structure-activity correlation for processed variants or fragments of SEQ ID NO: 2, a skilled artisan cannot predict which processed variant or fragment is functional. A few species of SEQ ID NO:2 or 1 (e.g., full length and residues 1-20, 5-24 and 2-13 of SEQ ID NO:2; full length of SEQ ID NO:1) does not provide sufficient written description for the whole genus of processed fragments or variants of SEQ ID NO: 2. The lack of description on the structure-activity correlation for processed peptides or corresponding nucleotides and lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

*Response to Arguments*

Applicants indicate claims 1-4 have been amended to limit the claimed amino acid sequence of SEQ ID No: 2 to an amino acid sequence that has a cardioinhibitory activity or hypotensive activity; an amino acid sequence where one to five amino acids are deleted, substituted or added, and an amino acid sequence having 80% or more homology to SEQ ID NO: 2. Furthermore, the instant specification (e.g., paragraphs 13 and 14) described that the claimed polypeptides are defined by their shared structural and functional features. The specification provides five working variants that span the entire scope of the claimed polypeptide genus, and further provides functional assays for identifying the polypeptides with such structural characteristics. Specifically, applicants provided (1) a polypeptide sequence, (2) activity/function, (3) a functional assay in the specification, and (4) the fact that certain regions of the peptide are tolerant to sequence modification and deletion, i.e., 1-4 and 14-24. Thus, in light of *Ex parte Sun* holding, the written description is satisfied, applicants respectfully request reconsideration and withdrawal of the written description rejection under 35 U.S.C. § 112, first paragraph (pages 10-13 of the response).

Applicants' response has been considered. Regarding the peptides of claim 1 and DNA of claim 3, applicants' arguments are found persuasive and the rejection of these claims is withdrawn. However, regarding claims 2, 4 and their dependent claims, the arguments are not found persuasive because the specification does not identify any peptide that is generated from the amino acid sequence (A) or (B) as a result of further cleavage or modification by a processing enzyme, nor describes the cleavage or modification by a processing enzyme, a skilled artisan cannot predict which processed peptide is functional. The lack of description of these

processed peptides in the specification, applicants have failed to sufficiently describe the claimed invention. Therefore, the rejection of claims 2, 4 and dependent claims are maintained.

***New Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 3 is indefinite because claim 3, part (E) recites a phrase "a DNA encoding a peptide consisting a nucleotide sequence……, and having a cardioinhibitory activity or hypotensive activity". The phrase cited renders the claim indefinite, it is not clear how a DNA encoding a peptide can have a cardioinhibitory activity or hypotensive activity.

***New Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claim 3 is rejected under 35 U.S.C. 102(b) as anticipated by Carulli *et al.* (WO 01/32875).

Carulli *et al.* disclose a human-derived DNA sequence (SEQ ID NO:1 or SEQ ID NO:3 of WO document) encoding a TorC polypeptide (SEQ ID NO: 2 or SEQ ID NO:4 of WO

document) comprising the instant amino acid sequence of SEQ ID NO:2 (See the attached sequence match; Tables 1 and 2, pages 6-8; claim 3).

***Claim Objections***

12. Claims 6 and 8 are objected to because the claims are dependent from a rejected claim, claim 3.

***Conclusion***

13. Claims 2-5, 7, 9 and 12-14 are rejected; and claims 6 and 8 are objected to. It appears that claim 1 is free of art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/
Primary Examiner, Art Unit 1656

CMK

November 14, 2009